

PATENT COOPERATION TREATY

(4/2004) 41

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:	Winckels, J.H.F. VEREENIGDE Nieuwe Parklaan 97 NL-2587 BN The Hague PAYS BAS
	04-06-05 (9:00h)
	26 JAN 2005
	ONTVANGEN
	28 JAN 2005
	AMERSFOORT
Applicant's or agent's file reference	P62684PC00

**NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

(PCT Rule 71.1)

date of mailing
(day/month/year)

21.01.2005

IMPORTANT NOTIFICATION		
International application No. PCT/NL 03/00851	International filing date (day/month/year) 02.12.2003	Priority date (day/month/year) 04.12.2002
Applicant COOPERATIEVE VERKOOP- EN PRODUCTIEVER.... ET AL		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P62684PC00	FOR FURTHER ACTION <small>See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)</small>																	
International application No. PCT/NL 03/00851	International filing date (day/month/year) 02.12.2003	Priority date (day/month/year) 04.12.2002																
International Patent Classification (IPC) or both national classification and IPC A01H5/00																		
Applicant COOPERATIEVE VERKOOP- EN PRODUCTIEVER.... ET AL																		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>																		
<p>3. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: right; padding-right: 5px;">I</td> <td style="width: 90%; padding-left: 5px;"><input checked="" type="checkbox"/> Basis of the opinion</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">II</td> <td style="padding-left: 5px;"><input type="checkbox"/> Priority</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">III</td> <td style="padding-left: 5px;"><input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">IV</td> <td style="padding-left: 5px;"><input type="checkbox"/> Lack of unity of invention</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">V</td> <td style="padding-left: 5px;"><input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">VI</td> <td style="padding-left: 5px;"><input type="checkbox"/> Certain documents cited</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">VII</td> <td style="padding-left: 5px;"><input type="checkbox"/> Certain defects in the international application</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">VIII</td> <td style="padding-left: 5px;"><input type="checkbox"/> Certain observations on the international application</td> </tr> </table>			I	<input checked="" type="checkbox"/> Basis of the opinion	II	<input type="checkbox"/> Priority	III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/> Lack of unity of invention	V	<input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/> Certain documents cited	VII	<input type="checkbox"/> Certain defects in the international application	VIII	<input type="checkbox"/> Certain observations on the international application
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Date of submission of the demand 11.06.2004	Date of completion of this report 21.01.2005																	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Holtorf, S Telephone No. +31 70 340-2827																	

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JC20 Rec'd PCT/PTO 01 JUN 2005

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/NL 03/00851

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-19 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/4-44 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/NL 03/00851

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	9-12,14
	No: Claims	1-6,7,8,13
Inventive step (IS)	Yes: Claims	
	No: Claims	1-14
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/NL 03/00851

1. The following documents are considered relevant for the current application:

- D1: Jacobsen et al. Euphytica, 1991
- D2: Hovenkamp-Hermelink et al. TAG, 1987
- D3: Kortstee et al. The Plant Journal, 1996
- D4: WO0148230

Re Item V.

2. Novelty (Art. 33(2) PCT)

2.1 Claims 1-6,13 do not meet the requirements of Art. 33(2) PCT in that the matter for which protection is sought is not new.

Potato plants having at least one amf-allele are already known in the prior art (see document D1 and D2); the increased protein content of these plants is an intrinsic property of such plants carrying at least one amf-allele. Thus, the potato plants of documents D1 and D2 are identical to the subject-matter of claims 1-6,13 and they do not become novel when defined by different parameters.

2.2 Furthermore, the subject-matter as defined in claims 7 and 8 is not new with respect to Art. 33(2) PCT. Document D3 is disclosing an amf-allele containing mutant potato plant transformed with the *E. coli* *glgB* transgene under control of the GBSS promoter.

3. Inventive Step ((Art.33 (3) PCT))

3.1 WO0148230 (D4), which represents the closest prior art, discloses potato plants with an enhanced content essential amino acids in their tubers by expressing a potato gene

encoding a feedback insensitive dihydrodipicolinate synthase (DHPS).

3.2 The difference between D4 and the current application is the use of an additional sink-protein to trap the essential amino acids and the use of potato host plants that exhibit an increased protein storage capacity.

3.3 The problem is characterized as the provision of an improved system of adequate sink-proteins and better potato host plants to further increase the amount of essential amino acids in potato tubers.

3.4 The solution is the simultaneous expression of the DHPS (providing essential amino acids) and the Multicystatin (as sink protein trapping the essential amino acids) in amf-allele carrying potato plants.

3.5 amf-allele carrying potato plants have already been identified and their starch quality and content has been analysed. The prior art does not disclose that the amf-allele carrying potato plants also exhibit an increased protein storage capacity and the prior art does neither teach nor suggests to use said plants as a host system for the expression of genes of interest to enhance the level of essential amino acids in plants.

3.6 However, due to the fact that no experimental evidence is provided showing the successful generation of potato plants carrying the amf-allele and transformed with a construct harbouring the DHPS and the Multicystatin gene, the problem of the current application appears to have not been solved.

In the absence of experimental data demonstrating the successful increasing of the content of essential amino acids in amf-allele containing potato plants as compared to commonly used potato cultivars, it is at present not possible to acknowledge and inventive step for the subject-matter of claims 7-9 with respect to Art. 33(3) PCT.

4. Essentially biological processes and plant varieties (Rule 67.1 (ii) PCT)

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/NL 03/00851

4.1 Claims 10-12,14 are directed to methods of crossing a first amf-allele carrying potato plant with a second potato plant not carrying the amf-allele and testing and selecting the progeny for improved characteristics and further - in claim 13 - to the potato plants obtained by said method and the use of said potato plants for a breeding and selection programme.

The method of claims 10-12,14 is representing an essentially biological process for the production of plants and is therefore characterizing subject matter which falls under Rule 67.1 (ii) PCT. The same applies for the obtained plants as characterized in claim 13 which originate from said methods.

The method of claim 10 consists essentially of natural phenomena such as crossing and selection, such methods are used by the ordinary breeder to obtain novel plants with improved characteristics/traits. The essence of claims 10-14 is non-technical.